Message

From: Pease, Anita [Pease.Anita@epa.gov]
Sent: 5/12/2020 9:00:09 PM
To: Keigwin, Richard [Keigwin.Richard@epa.gov]
Subject: FW: Question about GLP requirements for antimicrobial products

Ex. 5 Deliberative Process (DP)

Anita Pease
Director, Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency

703-305-0392
pease.anita@epa.gov

From: Willis, Kristen <Willis.Kristen@epa.gov>
Sent: Tuesday, May 12, 2020 4:56 PM
To: Pease, Anita <Pease.Anita@epa.gov>; Hebert, John <Hebert.John@epa.gov>; Kyprianou, Rose <Kyprianou.Rose@epa.gov>
Cc: Weiss, Steven <Weiss.Steven@epa.gov>
Subject: RE: Question about GLP requirements for antimicrobial products

Ex. 5 Deliberative Process (DP)

From: Pease, Anita <Pease.Anita@epa.gov>
Sent: Tuesday, May 12, 2020 4:50 PM
To: Willis, Kristen <Willis.Kristen@epa.gov>; Hebert, John <Hebert.John@epa.gov>; Kyprianou, Rose <Kyprianou.Rose@epa.gov>
Cc: Weiss, Steven <Weiss.Steven@epa.gov>
Subject: FW: Question about GLP requirements for antimicrobial products

Ex. 5 Deliberative Process (DP)

Thanks,
Anita

Anita Pease
Director, Antimicrobials Division

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U.S. Environmental Protection Agency

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From: Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>
Sent: Monday, May 4, 2020 3:14 PM
To: Pease, Anita <Pease.Anita@epa.gov>
Cc: Pittman, Forrest <Pittman.Forrest@epa.gov>; Willis, Kristen <Willis.Kristen@epa.gov>
Subject: FW: Question about GLP requirements for antimicrobial products

Anita, below is Forrest's response to the GLP question that Kristen had sent our way. While this appears to be a separate inquiry from the one you emailed Rick about (and cc'd me on that email), I think Forrest's response does at least begin to speak to your seemingly separate situation. Ex. 5 AC/DP

Ex. 5 AC/DP

Ex. 5 AC/DP If we are missing the point here, though, and you need additional input from us on any of this, please let Forrest and me know. Thanks, Chris

Chris E. Kaczmarek
Assistant General Counsel
Pesticide and Toxic Substance Law Office
Office of General Counsel
U.S. EPA
Tel (202) 564-3909

From: Pittman, Forrest <Pittman.Forrest@epa.gov>
Sent: Monday, May 04, 2020 10:35 AM
To: Willis, Kristen <Willis.Kristen@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>
Subject: RE: Question about GLP requirements for antimicrobial products

Kristen,

Ex. 5 AC/DP

Let me know if you want to discuss, or if there are any more questions that you'd like me to look into on this matter.

Thanks,

Forrest Pittman
Pesticides and Toxic Substances Law Office
U.S. EPA Office of General Counsel
(202) 564-9626

From: Willis, Kristen
Sent: Tuesday, 28 April, 2020 14:55
To: Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>; Pittman, Forrest <Pittman.Forrest@epa.gov>
Subject: Question about GLP requirements for antimicrobial products

Hi Chris and Forrest,

I was hoping to get your interpretation on GLP requirements for efficacy testing to support antimicrobial claims. We are starting to receive requests from registrants wanting to know if the GLP testing requirement could be waived/suspended/conditional due to long lead times for commercial GLP-testing labs. Rather that have tests conducted at one of the labs, the company would conduct testing in house, at their own R&D (non-GLP) lab. I have attached our efficacy guideline that covers general considerations. The following from section B(4) is the most relevant:

"**Good Laboratory Practice Standards.** Good Laboratory Practice (GLP) Standards as defined in 40 CFR Part 160 apply to studies submitted to support the registration or amendment of antimicrobial products with public health claims. According to 40 CFR §160.17: "EPA may refuse to consider reliable for purposes of supporting an application for a research or marketing permit any data from a study which was not conducted in accordance with this part." 40 CFR §160.12 requires any study submitted to EPA to support an application for a research or marketing permit to include statements signed by the applicant that "[a] the study was conducted in accordance with this part; [b] describing in detail all differences between the practices used in the study and those required by this part; or [c] that the person was not a sponsor of the study, did not conduct the study, and does not know whether the study was conducted in accordance with this part."

Ex. 5 AC/DP

Would appreciate any thoughts or guidance you could provide.

Thanks,
Kristen Willis

Kristen Willis, PhD
Branch Chief
Product Science Branch
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Environmental Protection Agency

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Cell: 571-289-9260

Conference Line: **Ex. 6 PP - conference code/call in number**
ID: **Ex. 6 PP - conference code/call in number**